

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004D-0146]

DDM

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Officer	A. Corbin

**Guidance for Industry: Validation of Analytical Procedures for Type C
Medicated Feeds; Availability**

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a final guidance for industry (#135) entitled "Validation of Analytical Procedures for Type C Medicated Feeds." This guidance represents the agency's current thinking on the characteristics that should be considered during the validation of non-microbiological analytical procedures for the analysis of drugs in Type C medicated feeds included as part of original and supplemental new animal drug applications (NADAs) and abbreviated new animal drug applications (ANADAs) for Type A medicated articles submitted to FDA. This guidance is the first in a series of three guidances that will discuss assay methods for Type C medicated feeds.

DATES: Submit written or electronic comments on agency guidance documents at any time.

ADDRESSES: Submit written requests for single copies of the guidance to the Communications Staff (HFV-12), Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing your requests.

Submit written comments on the guidance to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Mary G. Leadbetter, Center for Veterinary Medicine (HFV-141), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-6964, e-mail: mleadbet@cvm.fda.gov.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of April 28, 2004 (69 FR 23209), FDA published a notice of availability for a draft guidance entitled “Validation of Analytical Procedures for Type C Medicated Feeds” giving interested persons until July 12, 2004, to comment on the draft guidance. FDA received no comments on the draft guidance and no substantive changes were made in finalizing this guidance document.

II. Paperwork Reduction Act of 1995

According to the Paperwork Reduction Act of 1995, a collection of information must display a valid OMB control number. The existing valid OMB control numbers for this information collection are 0910-0032 and 0910-0154. This guidance contains no new collections of information.

III. Significance of Guidance

This level 1 guidance is being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115). This guidance represents the agency’s current thinking on the topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternate

method may be used as long as it satisfies the requirements of applicable statutes and regulations.

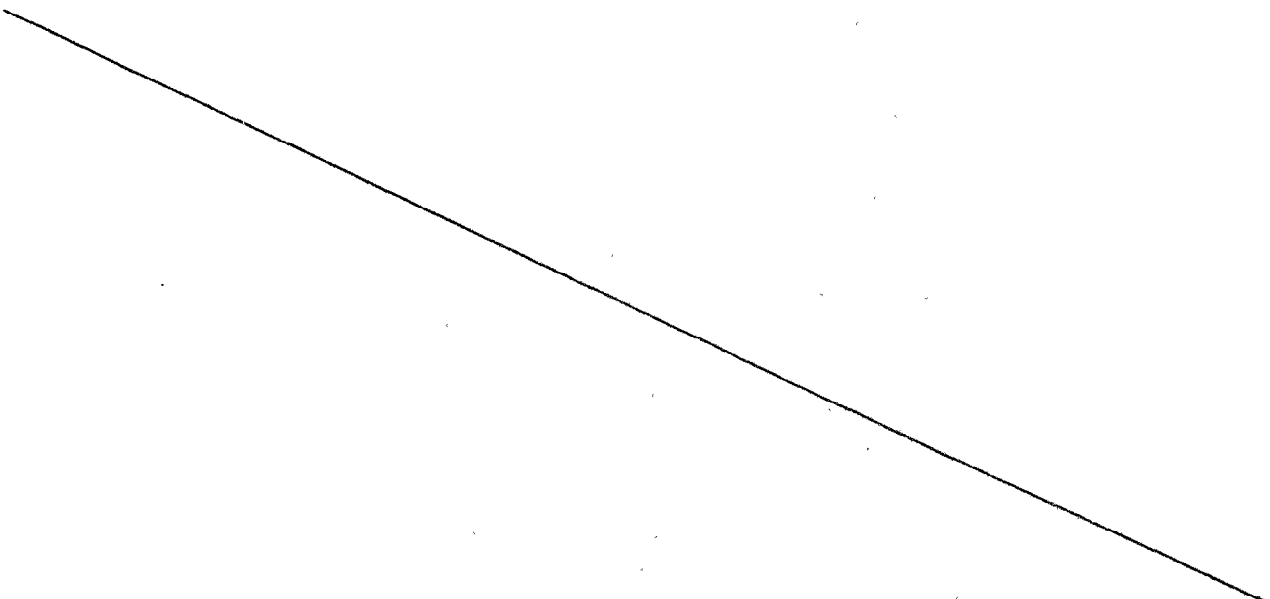
IV. Comments

As with all FDA's guidances, the public is encouraged to submit written or electronic comments with new data or other new information pertinent to this guidance. FDA periodically will review the comments in the docket, and where appropriate, will amend the guidance. The agency will notify the public of any such amendments through a notice in the **Federal Register**.

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments on the guidance at any time. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments should be identified with the docket number found in brackets in the heading of this document. A copy of the document and received comments are available for public examination in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

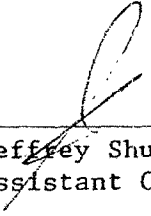
V. Electronic Access

Copies of the guidance document entitled "Validation of Analytical Procedures for Type C Medicated Feeds" may be obtained from the CVM Home



Page (<http://www.fda.gov/cvm>) and from the Division of Dockets Management
Web site (<http://www.fda.gov/ohrms/dockets/default.htm>).

Dated: 10/31/05
October 31, 2005.



Jeffrey Shuren,
Assistant Commissioner for Policy.

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